

K250994 ClearTip FNA and FNB TypesAug 21, 2025
142 days to decisionK250994 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Apr 1, 2025
Decision date	Aug 21, 2025
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Finemedix Co., Ltd.
Location	Daegu, KR
Contact	Priscilla Chung
510(k) history	11 submissions · 11 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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